

**REMARKS**

***Specification Amendment***

A substitute Abstract of the Disclosure is being submitted herewith, which Abstract is directed to the elected invention as presently claimed, and is of a reduced length having only 94 words as calculated by Microsoft Word.

***Claim Amendments***

Independent compound claim 5 has been amended to specify that the salt is a “pharmaceutically acceptable” salt, and elected claim 10 has been amended to be consistent therewith. Claim 12 has been newly cancelled as now being redundant.

Independent claim 5 and dependent claim 7 have been amended to correct the recitation “wherein Q<sup>14</sup> is linked to ~~C<sub>1-4</sub>alkanoyl-C<sub>1-6</sub>alkanoyl~~ through a nitrogen atom” That this was an error and the appropriate correction thereof would have been readily apparent to the skilled person since Q<sup>14</sup> is a part of the group “C<sub>1-4</sub>alkyl-Q<sup>13</sup>-C(O)-C<sub>1-4</sub>alkyl-Q<sup>14</sup>.”

Dependent compound claims 6-10 have been amended to more appropriately refer to “the” compound of the claim upon which they are dependent.

Dependent claim 10 has been amended to be wholly within the scope of the elected invention as claimed in independent claim 5.

Dependent claim 11 has been cancelled inasmuch as the recited compounds are also listed in dependent claim 10. Contrary to the Examiner’s apparent assertion, the compounds that were recited in claim 11 were all within the scope of the elected invention as claimed in independent claim 5.

Withdrawn process for making claim 13 has been cancelled.

Withdrawn method of treatment claim 16 has been amended to remove the phrase “such as a human being,” in that such phrases by way of example are not generally appropriate under U.S. practice.

The above amendments are being made without disclaimer or prejudice to Applicant's right to pursue any subject matter deleted thereby in one or more divisional or continuing applications.

It should be clear from the above that no new matter has been added by the above amendments, and entry of these amendments is therefore believed to be appropriate and is respectfully requested. Following entry of these amendments, claims 5-10, 14 and 16 remain pending in this application with claim 16 being designated as "withdrawn" pending rejoinder upon allowance of a generic compound claim upon which it is dependent.

***Comments on Restriction Requirement/Election***

The Examiner has withdrawn claims 8, 11, 13 and 16 from further consideration as being drawn to a nonelected invention, and has asserted that "a complete reply to this action must include cancellation of nonelected claims or other appropriate action." The reason for the Examiner's assertion with respect to dependent compound claims 8 and 11 is not understood, because claims 8 and 11 are fully within the elected invention as claimed in independent claim 5 and are properly presented for examination in this application. However, inasmuch as the three compounds recited in claim 11 are also recited in compound claim 10, claim 11 has been cancelled.

Non-elected process for making claim 13 and method of treatment claim 16 had been maintained in this application, but designated as withdrawn pending rejoinder for examination in this application upon allowance of a generic compound claim upon which they are dependent (*i.e.*, encompass all limitations thereof). The Examiner's attention is drawn to the second full paragraph on page 4 of the Restriction Requirement with regard to rejoinder of withdrawn process claims. Rather than making the extensive amendments needed to keep process-for-making claim 13 consistent with elected compound claim 5, Applicant has chosen to cancel claim 13, without prejudice to presenting it in a continuing application. However, method of treatment claim 16 is fully consistent with claim 5 upon which it is dependent, and has properly been maintained in

this application, designated as “withdrawn” pending rejoinder upon allowance of a compound claim upon which it is dependent.

In view of the above, compound claim 8 is directed toward the elected invention and properly has been maintained in this application and entitled to examination with the other elected claims. Non-elected method of treatment claim 16 has also been properly maintained pending, but designated as withdrawn pending rejoinder as explained above.

***Objection to Specification (Abstract)***

The substitute Abstract presented herewith has a word count of only 94 words (as calculated by Microsoft Word), and therefore this objection to the specification has been overcome.

***Claim Objections***

Claims 9 and 12 have been objected to because they are dependent on allegedly “withdrawn” claims 8 and 11. As explained above, claims 8 and 11 were fully within the scope of the elected invention as claimed in claim 5, and therefore this objection was not well founded and should be withdrawn. Moreover, the objection with respect to claim 12 has been obviated by the cancellation of claim 12.

***Obviousness-Type Double Patenting - U.S. Patent No. 7,074,800***

Claims 5-7, 9, 10, 12, and 14 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-25 of U.S. Patent No. 7,074,800 (hereinafter “US ‘800”). As background and as previously discussed at pages 16-17 of Applicant’s September 24, 2009 response in this application, US ‘800 issued on the US National Stage application corresponding to the International Application that published as WO 00/47212 on August 17, 2000 (also cited at page 3 of the present specification), and divisional Application 11/169,122 was filed therefrom and published as US 20060004017 and is currently pending.

As the basis for this rejection the Examiner asserts at page 4 of the Action that “although the conflicting claims are not identical, they are not patentably distinct from

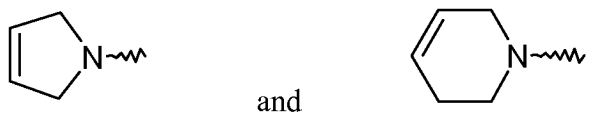
each other *because there is significant overlap between the two applications,*” [emphasis added] and continues:

The genus structure seen in claim 1 of patent '800 may fully encompass the instantly claimed compounds and/or give structurally similar compounds. For instance in the instant application, compounds wherein  $n_c = 0$ ,  $M = CH$ ,  $R^{2d} = H$ ,  $Z^a = O$ ,  $R^{2a} = H$ , and  $R^{2b} =$  -Opyrrolidinyl substituted with  $C_{2-4}$ alkanoyl $C_{1-3}$ alkyl may fall within the genus structure of claim 1 and/or give homologous compounds; thus rendering the instantly claimed compounds obvious.

This ground for rejection is respectfully traversed in that there is *no overlap* of either the claims or the specification disclosure of the US '800 patent with the scope of the present claims. More specifically, the presently claimed compound do not lie within the scope of either the claims or the disclosure of US '800 because in the present claims at least one of  $R^{2a}$  and  $R^{2b}$  at the 6- and 7-positions of the quinazoline ring *must* be  $Q^1X^1$ , and the values for  $Q^1X^1$  do not lie within the scope of the US '800 patent.

As the group  $Q^1X^1$  is defined in **present independent claim 5**,  $X^1$  is O and  $Q^1$  is selected from one of three groups:

**In group 1)**,  $Q^1$  is defined as “ $C_{1-4}$ alkyl- $Q^{13}$ -C(O)- $C_{1-4}$ alkyl- $Q^{14}$  wherein  $Q^{13}$  and  $Q^{14}$  are each independently selected from pyrrolidinyl, piperidinyl, piperazinyl,



wherein  $Q^{14}$  is linked to  $C_{1-4}$ alkanoyl through a nitrogen atom.”

In contrast, there is no possibility in the compounds defined in US '800 for the 6- or 7-position substituent to have two saturated (or partially saturated) heterocyclic rings being joined by a -C(O)- $C_{1-4}$ alkyl- group. A side chain with two saturated (or partially saturated) heterocyclic rings can come about in US '800 where  $R^2$  is  $R^5X^1$ , where  $X^1$  is -O- and  $R^5$  is defined as  $R^{28}$  in group 5) as follows:

- 5)  $R^{28}$  (wherein  $R^{28}$  is a 5-6-membered saturated heterocyclic group (linked via carbon or nitrogen) with 1-2 heteroatoms, selected independently from O, S and N, *which heterocyclic group may bear 1*

or 2 substituents selected from oxo, hydroxy, halogeno, cyano, C<sub>1-4</sub>cyanoalkyl, C<sub>1-4</sub>alkyl, C<sub>1-4</sub>hydroxyalkyl, C<sub>1-4</sub>alkoxy, C<sub>1-4</sub>alkoxyC<sub>1-4</sub>alkyl, C<sub>1-4</sub>alkylsulphonylC<sub>1-4</sub>alkyl, C<sub>1-4</sub>alkoxycarbonyl, C<sub>1-4</sub>aminoalkyl, C<sub>1-4</sub>alkylamino, di(C<sub>1-4</sub>alkyl)amino, C<sub>1-4</sub>alkylaminoC<sub>1-4</sub>alkyl, di(C<sub>1-4</sub>alkyl)aminoC<sub>1-4</sub>alkyl, C<sub>1-4</sub>alkylaminoC<sub>1-4</sub>alkoxy, di(C<sub>1-4</sub>alkyl)aminoC<sub>1-4</sub>alkoxy and a group  $-(O)_f(C_{1-4}alkyl)_g ringD$  (wherein  $f$  is 0 or 1,  $g$  is 0 or 1 and ring D is a 5-6-membered saturated heterocyclic group with 1-2 heteroatoms, selected independently from O, S and N, which cyclic group may bear one or more substituents selected from C<sub>1-4</sub>alkyl));

(Col. 8, lines 61-67; claim 1, col. 242, line 63 to col. 243, line 12; emphasis added); or alternatively if R<sup>5</sup> is defined as in group 22) as follows:

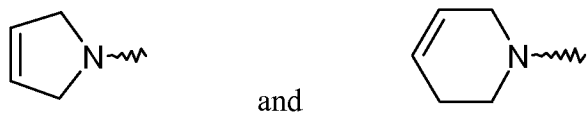
22) C<sub>1-4</sub>alkylR<sup>54</sup>(C<sub>1-4</sub>alkyl)<sub>q</sub>(X<sup>9</sup>)<sub>r</sub>R<sup>55</sup> (wherein X<sup>9</sup> is as defined hereinbefore [wherein X<sup>9</sup> represents -O-, -S-, -SO-, -SO<sub>2</sub>-, -NR<sup>49</sup>C(O)-, -C(O)NR<sup>50</sup>-, -SO<sub>2</sub>NR<sup>51</sup>-, -NR<sup>52</sup>SO<sub>2</sub>- or -NR<sup>53</sup>- (wherein R<sup>49</sup>, R<sup>50</sup>, R<sup>51</sup>, R<sup>52</sup> and R<sup>53</sup> each independently represents hydrogen, C<sub>1-3</sub>alkyl or C<sub>1-3</sub>alkoxyC<sub>2-3</sub>alkyl) ],  $q$  is 0 or 1,  $r$  is 0 or 1, and R<sup>54</sup> and R<sup>55</sup> are each independently selected from hydrogen, C<sub>1-3</sub>alkyl, cyclopentyl, cyclohexyl and a 5-6-membered saturated heterocyclic group with 1-2 heteroatoms, selected independently from O, S and N, which C<sub>1-3</sub>alkyl group may bear 1 or 2 substituents selected from oxo, hydroxy, halogeno and C<sub>1-4</sub>alkoxy and which cyclic group may bear 1 or 2 substituents selected from oxo, hydroxy, halogeno, cyano, C<sub>1-4</sub>cyanoalkyl, C<sub>1-4</sub>alkyl, C<sub>1-4</sub>hydroxyalkyl, C<sub>1-4</sub>alkoxy, C<sub>1-4</sub>alkoxyC<sub>1-4</sub>alkyl, C<sub>1-4</sub>alkylsulphonylC<sub>1-4</sub>alkyl, C<sub>1-4</sub>alkoxycarbonyl, C<sub>1-4</sub>aminoalkyl, C<sub>1-4</sub>alkylamino, di(C<sub>1-4</sub>alkyl)amino, C<sub>1-4</sub>alkylaminoC<sub>1-4</sub>alkyl, di(C<sub>1-4</sub>alkyl)aminoC<sub>1-4</sub>alkyl, C<sub>1-4</sub>alkylaminoC<sub>1-4</sub>alkoxy, di(C<sub>1-4</sub>alkyl)aminoC<sub>1-4</sub>alkoxy and a group  $-(O)_f(C_{1-4}alkyl)_g ringD$  (wherein  $f$  is 0 or 1,  $g$  is 0 or 1 and ring D is a 5-6-membered saturated heterocyclic group with 1-2 heteroatoms, selected independently from O, S and N, which cyclic group may bear one or more substituents selected from C<sub>1-4</sub>alkyl), with the proviso that R<sup>54</sup> cannot be hydrogen);

(col. 4, line 55 to col. 6, line 9; claim 1, col. 244, lines 14-36; emphasis added).

Thus, contrary to the **group 1)** definition of Q<sup>1</sup> in present claim 5, there is no possibility in the compounds defined in US '800 for the 6- or 7-position substituent to have two saturated (or partially saturated) heterocyclic rings joined by a -C(O)-C<sub>1-4</sub>alkyl- group.

**In groups 2) and 3)** of present claim 5, Q<sup>1</sup> is defined as:

2) Q<sup>2</sup> (wherein Q<sup>2</sup> is a 5-6-membered heterocyclic group selected from pyrrolidinyl, piperidinyl, piperazinyl,



which heterocyclic group bears either one substituent selected from methylenedioxy or ethylenedioxy to form a bicyclic ring, or bears at least one substituent selected from C<sub>2-4</sub>alkanoylC<sub>1-3</sub>alkyl ...; and

3) C<sub>1-5</sub>alkylQ<sup>2</sup> (wherein Q<sup>2</sup> is as defined herein);

In contrast, there is no possibility in the compounds defined in US '800 for the 6- or 7-position substituent to have at least one substituent selected from C<sub>2-4</sub>alkanoylC<sub>1-3</sub>alkyl or a saturated (or partially saturated) heterocyclic ring bearing a substituent selected from methylenedioxy and ethylenedioxy to form a bicyclic ring. Reference is again made to the above discussion of US '800 and the definition of group 5) of the definition of R<sup>2</sup> for the definition of R<sup>28</sup> in the specification and in claim 1.

Accordingly, contrary to the Examiner's assertion, there is no overlap between the presently claimed compounds and the compounds disclosed or claimed in US '800, and this ground for rejection should be withdrawn.

***Obviousness-Type Double Patenting - U.S. Application No. 11/705035***

The Examiner has also provisionally rejected claims 5-7, 9, 10, 12, and 14 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2-18, 20, 23, 24, and 27 of copending Application No. 11/705035. As background and as previously discussed at pages 16-17 of Applicant's September 24, 2009 response in the present application, Application No. 11/705035 is a continuation of Application 10/502,538, which issued as US Patent No. 7,268,230, and which application was the US National Stage corresponding the International Application published as WO 03/064413 on August 7, 2003.

Again, the Examiner asserts at page 4 of the Action as the basis for this rejection that "although the conflicting claims are not identical, they are not patentably distinct from each other *because there is significant overlap between the two applications,*" [emphasis added] and continues in the paragraph bridging pages 4 and 5:

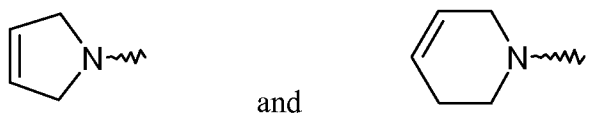
The genus structure seen in claim 27 of application 11/705035 may fully encompass the instantly claimed compounds and/or give structurally similar compounds. For instance in the instant application, compounds wherein  $nc = 0$ ,  $M = CH$ ,  $R^{2d} = H$ ,  $Z^a = O$ ,  $R^{2a} = H$ , and  $R^{2b} = -\text{Opyrrolidinyl}$  substituted with  $C_{2-4}\text{alkanoyl}C_{1-3}\text{alkyl}$  may fall within the genus structure of claim 27 and/or give homologous compounds; thus rendering the instantly claimed compounds obvious.

The Examiner notes that this is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented. This rejection remains provisional in that Application 11/705035 is still pending.

Nevertheless, this ground for rejection is respectfully traversed in that there is *no overlap* of either the claims or the specification disclosure of Application 11/705035 with the scope of the present claims. More specifically, the presently claimed compounds do not lie within the scope of either the claims or the disclosure of Application 11/705035 because in the present claims at least one of  $R^{2a}$  and  $R^{2b}$  at the 6- and 7-positions of the quinazoline ring *must* be  $Q^1X^1$ , and the values for  $Q^1X^1$  do not lie within the scope of the compound definitions of Application 11/705035.

As discussed above, the group  $Q^1X^1$  is defined in **present independent claim 5** with  $X^1$  being O and  $Q^1$  being selected from one of three groups:

**In group 1)**,  $Q^1$  is defined as " $C_{1-4}\text{alkyl}-Q^{13}-C(O)-C_{1-4}\text{alkyl}-Q^{14}$  wherein  $Q^{13}$  and  $Q^{14}$  are each independently selected from pyrrolidinyl, piperidinyl, piperazinyl,



wherein  $Q^{14}$  is linked to  $C_{1-4}\text{alkanoyl}$  through a nitrogen atom."

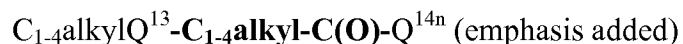
In contrast, there is no possibility in the compounds defined in Application 11/705035 for the 6- or 7-position substituent to have two saturated (or partially saturated) heterocyclic rings being joined by a  $-C(O)-C_{1-4}\text{alkyl}-$  group as in the present claims. The closest group in Application 11/705035 is in the definition of  $R^{2a}$  or  $R^{2b}$  at the 6- or 7-position of the quinazoline ring as  $Q^1X^1$  wherein  $X^1$  is O and  $Q^1$  is one of 10

groups, group 10) being defined as follows in original claim 1 and currently pending claim 27, and in the specification, *e.g.*, at page 12, lines 6-9:

- 10)  $C_{1-4}\text{alkyl}Q^{13}C_{1-4}\text{alkanoyl}Q^{14n}$  wherein  $Q^{13}$  is as defined herein and is not hydrogen and  $Q^{14n}$  is a 5-6-membered saturated or partially unsaturated heterocyclic group containing at least one nitrogen atom and optionally containing a further nitrogen atom wherein  $Q^{14n}$  is linked to  $C_{1-6}\text{alkanoyl}$  through a nitrogen atom ...

wherein  $Q^{13}$  can be “a 5-6-membered saturated or partially unsaturated heterocyclic group with 1-2 heteroatoms, selected independently from O, S and N.”

A key difference is that the linkage in Application 11/705035 is



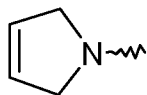
whereas in the present claim 5 the linkage is



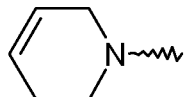
wherein  $Q^{13}$  and  $Q^{14}$  are as defined therein. This distinction is made clear by the definition of “alkanoyl” at page 56, lines 4-8 in Application 11/705035 (which definition also appears at page 40, lines 4-8 of the *present* application. Thus, there is no overlap between **group 1)** of present claim 5 and the compounds disclosed in Application 11/705035.

**In groups 2) and 3)** of present claim 5,  $Q^1$  is defined as:

- 2)  $Q^2$  (wherein  $Q^2$  is a 5-6-membered heterocyclic group selected from pyrrolidinyl, piperidinyl, piperazinyl,



and



,

which heterocyclic group bears either one substituent selected from methylenedioxy or ethylenedioxy to form a bicyclic ring, or bears at least one substituent selected from  $C_{2-4}\text{alkanoyl}C_{1-3}\text{alkyl}$  ...; and

- 3)  $C_{1-5}\text{alkyl}Q^2$  (wherein  $Q^2$  is as defined herein);



In contrast, there is no possibility in the compounds defined in Application 11/705035 for the 6- or 7-position substituent to have at least one substituent selected from C<sub>2-4</sub>alkanoylC<sub>1-3</sub>alkyl, or to have a saturated (or partially saturated) heterocyclic ring bearing a substituent selected from methylenedioxy and ethylenedioxy to form a bicyclic ring, as required in the definitions of groups 2) and 3) of present claim 5. The Examiner's attention is called to claim 27 now pending in Application 11/705035, and the following passage under the "proviso" with respect to R<sup>2</sup> being Q<sup>1</sup>X<sup>1</sup>-, where such substituents, *if included*, would most likely be recited:

(i) Q<sup>1</sup>X<sup>1</sup>- wherein X<sup>1</sup> is as defined herein<sup>1</sup> and Q<sup>1</sup> is selected from one of the following ten groups:

- 1) Q<sup>2</sup>, wherein Q<sup>2</sup> is a 5-6-membered saturated or partially unsaturated heterocyclic group with 1-2 heteroatoms, selected independently from O, S and N, which heterocyclic group bears at least one substituent selected from C<sub>2-5</sub>alkenyl, C<sub>2-5</sub>alkynyl, C<sub>1-6</sub>alkanoyl, aminoC<sub>1-6</sub>alkanoyl, C<sub>1-4</sub>alkylaminoC<sub>1-6</sub>alkanoyl, di(C<sub>1-4</sub>alkyl)aminoC<sub>1-6</sub>alkanoyl, C<sub>1-6</sub>fluoroalkanoyl, carbamoyl, C<sub>1-4</sub>alkylcarbamoyl, di(C<sub>1-4</sub>alkyl)carbamoyl, carbamoylC<sub>1-6</sub>alkyl, C<sub>1-4</sub>alkylcarbamoylC<sub>1-6</sub>alkyl, di(C<sub>1-4</sub>alkyl)carbamoylC<sub>1-6</sub>alkyl, C<sub>1-6</sub>alkylsulphonyl and C<sub>1-6</sub>fluoroalkylsulphonyl and which heterocyclic group may optionally bear a further 1 or 2 substituents selected from C<sub>2-5</sub>alkenyl, C<sub>2-5</sub>alkynyl, C<sub>1-6</sub>fluoroalkyl, C<sub>1-6</sub>alkanoyl, aminoC<sub>1-6</sub>alkanoyl, C<sub>1-4</sub>alkylaminoC<sub>1-6</sub>alkanoyl, di(C<sub>1-4</sub>alkyl)aminoC<sub>1-6</sub>alkanoyl, C<sub>1-6</sub>fluoroalkanoyl, carbamoyl, C<sub>1-4</sub>alkylcarbamoyl, di(C<sub>1-4</sub>alkyl)carbamoyl, carbamoylC<sub>1-6</sub>alkyl, C<sub>1-4</sub>alkylcarbamoylC<sub>1-6</sub>alkyl, di(C<sub>1-4</sub>alkyl)carbamoylC<sub>1-6</sub>alkyl, C<sub>1-6</sub>alkylsulphonyl, C<sub>1-6</sub>fluoroalkylsulphonyl, oxo, hydroxy, halogeno, cyano, C<sub>1-4</sub>cyanoalkyl, C<sub>1-4</sub>alkyl, C<sub>1-4</sub>hydroxyalkyl, C<sub>1-4</sub>alkoxy, C<sub>1-4</sub>alkoxyC<sub>1-4</sub>alkyl, C<sub>1-4</sub>alkylsulphonylC<sub>1-4</sub>alkyl, C<sub>1-4</sub>alkoxycarbonyl, C<sub>1-4</sub>aminoalkyl, C<sub>1-4</sub>alkylamino, di(C<sub>1-4</sub>alkyl)amino, C<sub>1-4</sub>alkylaminoC<sub>1-4</sub>alkyl, di(C<sub>1-4</sub>alkyl)aminoC<sub>1-4</sub>alkyl, C<sub>1-4</sub>alkylaminoC<sub>1-4</sub>alkoxy, di(C<sub>1-4</sub>alkyl)aminoC<sub>1-4</sub>alkoxy and a group -(O-)<sub>f</sub>(C<sub>1-4</sub>alkyl)<sub>g</sub>ringD wherein f is 0 or 1, g is 0 or 1 and ring D is a 5-6-membered saturated or partially unsaturated heterocyclic group

<sup>1</sup> The definition of X<sup>1</sup> earlier in claim 27 is "X<sup>1</sup> represents a direct bond, -O-, -CH<sub>2</sub>-, -OC(O)-, -C(O)-, -S-, -SO-, -SO<sub>2</sub>-, -NR<sup>6</sup>C(O)-, -C(O)NR<sup>7</sup>-, -SO<sub>2</sub>NR<sup>8</sup>-, -NR<sup>9</sup>SO<sub>2</sub>- or -NR<sup>10</sup>-, wherein R<sup>6</sup>, R<sup>7</sup>, R<sup>8</sup>, R<sup>9</sup> and R<sup>10</sup> each independently represents hydrogen, C<sub>1-3</sub>alkyl or C<sub>1-3</sub>alkoxyC<sub>2-3</sub>alkyl."

with 1-2 heteroatoms, selected independently from O, S and N, which cyclic group may bear one or more substituents selected from C<sub>1-4</sub>alkyl;

(Application 11/705035, claim 27 presented in the October 12, 2007 Preliminary Amendment, the above-quoted paragraph bridging pages 29 and 30). However, clearly there is no inclusion of a C<sub>2-4</sub>alkanoylC<sub>1-3</sub>alkyl substituent, or a saturated (or partially saturated) heterocyclic ring bearing a substituent selected from methylenedioxy and ethylenedioxy to form a bicyclic ring, as required in the definitions of groups 2) and 3) of present claim 5.

Accordingly, contrary to the Examiner's assertion, there is no overlap between the presently claimed compounds and the compounds disclosed or claimed in Application 11/705035, and this ground for rejection should be withdrawn.

***Claim Rejections - 35 USC §112 (2<sup>nd</sup> Paragraph)***

Claims 10 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The cited basis for this ground for rejection is that claim 10 embraces compounds where the indole ring is attached via the oxygen atom at the 6-position contrary to the structure of formula IIb, and claim 12 depends on claim 12.

It is respectfully submitted that the above amendments to claim 10 obviate and overcome this ground for rejection of both claim 10 and claim 12, and this rejection should now be withdrawn.

***Claim Rejections - 35 USC §112 (1<sup>st</sup> Paragraph)***

Claims 5-7, 9, and 10 are rejected under 35 U.S.C. 112, first paragraph, on the assertion that the specification, "while being enabling for making and/or using pharmaceutically acceptable salts of the claimed compounds, does not reasonably provide enablement for using non-pharmaceutically acceptable salts of said compounds in the claimed method of use" and that "the specification does not enable any person skilled in the art of synthetic organic chemistry to make the invention commensurate in

scope with these claims.” While Applicant disagrees with the Examiner’s assertions upon which this rejection is based, in order to expedite the prosecution of this application to allowance the claims have been amended so that the only salts now being claimed are pharmaceutically acceptable salts. Thus this ground for rejection has been overcome and should be withdrawn.

### ***Conclusion***

All grounds for rejection having been addressed by the above amendments and/or remarks and, it is believed, overcome, it is respectfully requested that these grounds for rejection be withdrawn and that all claims be found allowable.

### ***Table of Related Applications***

The Examiner’s attention is directed to the following co-pending U.S. patents and patent applications of Applicants’ assignee, which may be considered technically related to the present application. The current status of each application as reported in the PAIR database is given in the right-hand column. Each of the published US applications and patents have been formally cited in a previously submitted Information Disclosure Statement, and a copy of each listed published PCT application has been submitted with a previously filed Information Disclosure Statement.

It is assumed that the Examiner has ready electronic access to each of the listed US applications, but the undersigned will provide a copy of any document from these files if requested by the Examiner.

<b>Inventor</b>	<b>U.S. Serial No. Filing Date</b>	<b>U.S. Pub. No. Publication Date</b>	<b>PCT Pub.No. PCT Pub. Date</b>	<b>Status</b>
Stokes <i>et al.</i>	09/913,020 May 6, 2002	7,074,800 July 11, 2006	WO 2000/47212 August 17, 2000	Patented
Stokes <i>et al.</i>	11/169,122 June 29, 2005	US 20060004017 January 5, 2006	WO 2000/47212 August 17, 2000	Assigned to Examiner Tamthom Ngo Truong in GAU 1624; Final Rejection Mailed 03- 18-2010
Hennequin	10/502,538 July 28, 2004	7,268,230 September 11, 2007	WO 2003/064413 August 07, 2003	Patented

<b>Inventor</b>	<b>U.S. Serial No. Filing Date</b>	<b>U.S. Pub. No. Publication Date</b>	<b>PCT Pub.No. PCT Pub. Date</b>	<b>Status</b>
Hennequin	11/705,035 February 12, 2007	US 20080027069 January 31, 2008	WO 2003/064413 August 07, 2003	Assigned to Examiner Tamthom Ngo Truong in GAU 1624; Ready for Examination
Hennequin	11/882,604 August 2, 2007	US 20090156821 June 18, 2009	WO 2003/064413 August 07, 2003	Abandoned

**EXCEPT** for issue fees payable under 37 C.F.R. § 1.18, the Director is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. §§ 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account 50-0310. This paragraph is intended to be a **CONSTRUCTIVE PETITION FOR EXTENSION OF TIME** in accordance with 37 C.F.R. § 1.136(a)(3).

Respectfully Submitted,  
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